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|--|----------------------|------------------------|-------------|
| <b>TRANSMITTAL<br/>FORM</b><br><i>(To be used for all correspondence after initial filing)</i> | Application Number   | 09/954,571             |             |
|  | Filing Date          | 09/11/2001             |             |
|  | First Named Inventor | Kenneth R. Chien       |             |
|  | Group Art Unit       | 1632                   |             |
|  | Examiner Name        | Peter Paras, Jr.       |             |
| Total Number of Pages in This Submission   | 6                    | Attorney Docket Number | 6627-PA0123 |

| ENCLOSURES (check all that apply)  |   |   |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input checked="" type="checkbox"/> Amendment / Response<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Response to Missing Parts Under<br>37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers<br>(for an Application)<br><input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and<br>Accompanying Petition<br><input type="checkbox"/> Petition to Convert to a Provisional<br>Application<br><input type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Small Entity Statement<br><input type="checkbox"/> Request for Refund | <input type="checkbox"/> After Allowance Communication to<br>Group<br><input type="checkbox"/> Appeal Communications to Board of<br>Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group<br>(Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Additional Enclosure(s)<br>(please identify below):<br>copy of office communication from PTO<br>(2 pp); return postcard |
| Remarks  |   |   |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT |                                      |
|--|--------------------------------------|
| ATTORNEY NAME                              | COLLEEN J. McKIERNAN Reg. No. 48,570 |
| FIRM                                       | BROWN, MARTIN, HALLER & McCLAIN, LLP |
| SIGNATURE                                  |                                      |
| DATE                                       | 1/10/03                              |

| CERTIFICATE OF MAILING   |                  |      |         |
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| I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date: 1/10/03 |                  |      |         |
| Typed or printed name  | Karen L. Johnson |      |         |
| Signature  |                  | Date | 1/10/03 |



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of )  
Kenneth R. Chien ) FOR: HIGH EFFICIENCY CARDIAC  
Serial No.: 09/954,571 ) GENE TRANSFER  
Filed: September 11, 2001 ) Group  
Art Unit: 1632

RESPONSE TO NOTIFICATION TO COMPLY WITH  
SEQUENCE LISTING REQUIREMENTS

Commissioner for Patents  
P. O. Box 2327  
Arlington VA 22202

Attention: Peter Paras, Jr.  
Examiner

Dear Sir:

This is in response to the Notice to Comply with Sequence Listing  
Requirements dated December 12, 2002 stating that the Applicant must provide a

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United States Postal Service as first class mail in an envelope addressed  
to: Commissioner for Patents, PO Box 2327, Arlington VA 22202 on

January 10, 2003

(Mailing Date)

Karen L. Johnson

(Typed Name)

*Karen L. Johnson*

(Signature)

January 10, 2003

(Date of Signature)

"Sequence Listing" and an amendment to direct its entry into the case.

The Applicants submit that no such listing is required in this case for a number of reasons. First, all of the sequences discussed in the application are first mentioned in the background section of the specification with references to where the sequences can be found. None of the sequences discussed in the instant application are new.

Second, the invention is directed to a method, not a composition of matter. The method teaches the use of a viral vector, not a specific nucleic acid sequence or even a specific nucleic acid. The invention is not limited by the selection of the viral vector. An exhaustive sequence listing could not be made. Dependent claims teach the use of adenovirus and adeno-associated virus vectors. However, adenovirus and adeno-associated virus are not a single virus, but instead families of viruses with many members, most likely with additional members to be identified. Therefore no exhaustive listing could be made. Moreover, those skilled in the art are readily able to identify the sequences of interest for use in the instant invention using NCBI-BLAST, SWISS-PROT or any of a number of databases containing nucleotide and protein sequence information or by referring to references listed in the text.

Third, just as the method is not limited by the choice of viral vector, it is also not limited by the coding sequence to be inserted. A number of examples of potentially useful coding sequences are presented in the specification, but they are not limitations of the method of the invention which is defined by the steps in claim 1. Again, the coding sequences for the examples given can be readily found in a sequence database or by referring to the references listed in the text.

Fourth, all sequences referred to in the application are referred to by name, not by the listing of a series of nucleotides or amino acids. Therefore, no listing is required.

The Applicants submit that in view of the above arguments that the application

is in proper form for examination and does not require a sequence listing.

### **FEES**


It is believed that no fees are due with this response. However, if a fee is due, the Commissioner is entitled to charge deposit account 02-4070 referencing case number 6627-PA123.

### **CONCLUSIONS**

In view of the above comments, the Applicants submit that the application is in proper form for examination. If the Examiner believes that examination of the case can be expedited by a telephone call, he is invited to call the agent for applicant listed below, collect, in order to resolve any issues that may remain.

Respectfully submitted,

Dated: January 10, 2003

By:   
Colleen J. McKiernan, PhD  
Agent for Applicant  
Registration No.48,570

BROWN MARTIN HALLER & McCLAIN LLP  
1660 Union Street  
San Diego, California 92101-2926

Telephone: (619) 238-0999  
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Docket No.: 6627-PA0123



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|                                 |             |   |                     |
|---------------------------------|-------------|---|---------------------|
| APPLICATION NO./<br>CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR /<br>PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
|---------------------------------|-------------|---|---------------------|

|          |
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| EXAMINER |
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|          |       |
|----------|-------|
| ART UNIT | PAPER |
|----------|-------|

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DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Sequence Compliance**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR 1.821(a)(1) and (a)(2). See Figure 1. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN A [REDACTED] PERIOD WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

To avoid damage to a CRF by irradiation, a reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>>, EFS Submission User Manual - ePAVE)
2. Mailed to: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. Mailed by Federal Express, United Parcel Service or other delivery service to: U. S. Patent and Trademark Office, 2011 South Clark Place, Customer Window, Box Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, Virginia 22202
4. Hand Carried directly to the Customer Window at: 2011 South Clark Place, Crystal Plaza Two, Lobby, Room 1B03, Box Sequence, Arlington, Virginia 22202

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242

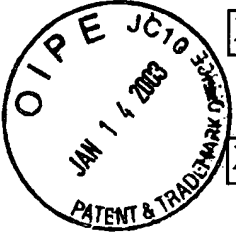
Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.  
Art Unit 1632

*Pete Paras*  
*Art Unit 1632*

# NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):



- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: \_\_\_\_\_

## Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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